Navigating the Center for Drug Evaluation and Research: What You Should Know for Effective Engagement

March 31st, 2016

8:00 a.m. Registration
8:30 a.m. Introduction and Opening Remarks
Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, FDA
John Whyte, MD MPH, Director, Professional Affairs and Stakeholder Engagement, FDA

SESSION ONE: BUILDING BLOCKS OF ENGAGEMENT...WHEN, WHY, AND HOW

8:45 a.m. Can You Hear Me Now? The Importance of Patient Engagement
John Whyte, MD MPH, Director, Professional Affairs and Stakeholder Engagement, FDA

9:00 a.m. An NDA at the FDA Understanding the Drug Approval Processes
Hank Hoang, PharmD, Pharmacist, Professional Affairs and Stakeholder Engagement, FDA

9:30 a.m. Engagement with the FDA
Richard A. Moscicki, MD, Deputy Center Director for Science Operations, FDA

9:55 a.m. FDA's Patient-Focused Drug Development
Pujita Vaidya, MPH, Operations Research Analyst, Office of Strategic Programs, FDA

10:25 a.m. Break

10:40 a.m. Drug Availability Shortages and Demand
CAPT Valerie Jensen, RPh, Associate Director of Drug Shortage Staff, FDA

11:00 a.m. Generic Drugs Busting the Myths
CAPT Jason Woo, MD MPH FACOG, Senior Medical Officer, Office of Generic Drugs, FDA

11:30 a.m. Lunch

1:00 p.m. Jeopardy Let’s Play Jeopardy

SESSION TWO – ENGAGEMENT...PUTTING THE PIECES TOGETHER

1:30 p.m. Making Sure My Meds Are Safe Manufacturers and Quality Controls
Brian Hasselbalch, Deputy Director, Office of Policy for Pharmaceutical Quality, FDA

1:55 p.m. The Small Print Reporting Side Effects
CAPT Catherine Chew, PharmD, Deputy Director, Division of Drug Information, FDA

2:20 p.m. ABC’s of OTC’s Little-Known Facts about Over-the-Counter Drugs
Karen Mahoney, MD, Deputy Director, Division of Nonprescription Drug Products, FDA

2:45 p.m. Break

3:00 p.m. Learn from the Pros Stories of Engagement from Advocacy Groups
Cynthia A. Bens, Vice President of Public Policy, Alliance for Aging Research
Bernadette O’Donoghue, Executive Director, Leukemia & Lymphoma Society

3:40 p.m. Final Words of Wisdom
John Whyte, MD MPH, Director, Professional Affairs and Stakeholder Engagement, FDA